K091742

Summary of Safety & Effectiveness
SYNCHRON® Systems
Enzymatic Creatinine (CR-E) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

June 11, 2009

AUG 14 2009

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems Enzymatic Creatinine (CR-E) Reagent

3.2 **Classification Name**
Enzymatic Method Creatinine (21 CFR § 862.1225)

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent	SYNCHRON Systems Creatinine (CR-S) Reagent	Beckman Coulter, Inc	K071283

5.0 **Description:**

CR-E reagent is used to measure the creatinine concentration by an enzymatic method. This enzymatic creatinine method utilizes a multi-step approach ending with a photometric end-point reaction.
The SYNCHRON Enzymatic Creatinine (CR-E) Reagent is designed for optimal performance on the SYNCHRON LX®, UniCel® DxC 600/800, and SYNCHRON CX® PRO Clinical Systems. The reagent kit contains two 200-test cartridges that are packaged separately from the associated calibrator.

6.0 **Intended Use:**

CR-E reagent, when used in conjunction with SYNCHRON® Systems, UniCel® DxC Systems and SYNCHRON® Systems AQUA CAL 1 and 2 and SYNCHRON CX® Calibrator Level 1 and 2, is intended for the quantitative determination of creatinine (CR-E) concentration in human serum, plasma or urine (urine is not available on the SYNCHRON CX® PRO Systems).

Clinical Significance:

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the candidate Enzymatic Creatinine (CR-E) Reagent and the predicate identified in Section 4.0 of this summary.

	Similarities	
SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent	Intended Use	Same
	Sample Types	Same for the LX/DxC Systems
	Instrument Platforms	Same
	Calibrator	Same
	Analytical range (Urine)	Same
	Differences	
SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent	Analytical range (Serum and Plasma)	CR-E Reagent: 0.2 – 25.0 mg/dL CR-S Reagent: 0.3 – 25.0 mg/dL
	Sample Types	CR-E Reagent: Plasma and Serum for CX Systems CR-S Reagent: Plasma, Serum and Urine for CX Systems
	Sample volume	CR-E Reagent: 10 µl (Serum, Plasma and Urine) Urine sample is diluted by the system at ratio of 1:10. CR-S Reagent: 20 µl Serum and Plasma, 3 µl Urine
	Reaction Type (Methodology)	CR-E Reagent: Enzymatic method CR-S Reagent: Modified rate Jaffe method
	Calibration Frequency	CR-E Reagent: Every 14 days CR-S Reagent: Every 5 days on LX/DxC Systems Every 7 days on CX Systems
	Detection Wavelength	CR-E Reagent: 560 nm (Primary Wavelength) CR-S Reagent: 520 nm (Primary Wavelength)

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Serum Method Comparison Summary

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
Enzymatic Creatinine (CR-E) Reagent	CX7 PRO	0.997	-0.002	1.000	78	SYNCHRON Systems Creatinine (CR-S) Reagent
	DxC800	0.991	0.012	1.000	80	

Urine Method Comparison Summary

Candidate	Platform	Slope	Intercept	R	N	Predicate Method
Enzymatic Creatinine (CR-E) Reagent	DxC800	0.988	-3.096	0.998	66	SYNCHRON Systems Creatinine (CR-S) Reagent

SYNCHRON Systems Enzymatic Creatinine (CR-E) Reagent Precision Study Results

Precision Study Results on SYNCHRON CX7 PRO Clinical System

Sample	Mean (mg/dL)	S.D.	%C.V.	N
Within-Run Imprecision				
Level 1	0.62	0.01	1.4	80
Level 2	4.16	0.02	0.5	80
Level 3	7.69	0.02	0.3	80
Human Pool	1.50	0.02	1.0	80
Total Imprecision				
Level 1	0.62	0.01	1.5	80
Level 2	4.16	0.02	0.6	80
Level 3	7.69	0.04	0.5	80
Human Pool	1.50	0.02	1.0	80

Precision Study Results on UniCel DxC 800 SYNCHRON Clinical System

Sample		Mean (mg/dL)	S.D.	%C.V.	N
Within-Run Imprecision					
Serum	Level 1	0.64	0.01	2.1	80
	Level 2	4.09	0.01	0.3	80
	Level 3	7.56	0.03	0.3	80
	Human Pool	1.50	0.01	0.7	80
Urine	Level 1	66.45	0.31	0.5	80
	Level 2	146.61	0.60	0.4	80
Total Imprecision					
Serum	Level 1	0.64	0.02	2.5	80
	Level 2	4.09	0.03	0.7	80
	Level 3	7.56	0.06	0.8	80
	Human Pool	1.50	0.01	0.9	80
Urine	Level 1	66.45	0.68	1.0	80
	Level 2	146.61	1.47	1.0	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993

Beckman Coulter, Inc.
c/o Ms. Marine Boyajian
Senior Regulatory Affairs Specialist
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Brea, CA 92822

AUG 14 2009

Re: k091742
Trade Name: Synchron Systems Enzymatic Creatinine (CR-E) Reagent
Regulation Number: 21 CFR §862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Codes: JFY
Dated: June 11, 2009
Received: June 16, 2009

Dear Ms. Boyajian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k091742

Device Name: SYNCHRON® Systems Enzymatic Creatinine (CR-E) Reagent

Indication For Use:

CR-E reagent, when used in conjunction with SYNCHRON® Systems, UniCel® DxC Systems and SYNCHRON® Systems AQUA CAL 1 and 2 and SYNCHRON CX® Calibrator Level 1 and 2, is intended for the quantitative determination of creatinine (CR-E) concentration in human serum, plasma or urine (urine is not available on the SYNCHRON CX® PRO Systems).

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091742